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Date: February 7, 2005

SUBJECT: Product Chemistry Review of IMS para-dichlorobenzene TGAI / MUP

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02-07-05

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DP BARCODE: D304943
DECISION No.: 345116
EPA REG. NO.: 81433-R
PRODUCT: p-dichlorobenzene TGAI / MUP
PCC : 061501
REGISTRANT: IMS Trading, LLC
USE: Insecticide

INTRODUCTION:

The registrant has submitted an application for the registration for the TGAI / MUP p-dichlorobenzene. The TGAI/MUP is manufactured by [redacted] In support the registrant has submitted product chemistry data under MRID No 462853-01 & 464606-01, the CSF for basic formulation (dated May 10, 2004) and the product label. The registrant has claimed that the proposed technical/MUP is substantially similar to the registered product with Reg. No. 1475-21. TRB has been asked to evaluate the product chemistry data submitted for TGAI/MUP and determine its similarity to the registered product.

SUMMARY OF FINDINGS:

1. The registrant has submitted a Confidential Statement of Formula for alternate formulation (dated 05-10-04) for the proposed TGAI / MUP. The average purity of the technical / MUP was 99.8%, as determined by the five batch analysis. The proposed certified limits for the AI are in accordance with standard limits as described in 40CFR§158.175(b)(2). The product chemistry data submitted corresponding to guideline reference 830.1550 (product identity & composition) and 830.1750 (certified limits) satisfy the data requirements of 40CFR§158.155 and 158.175 respectively [MRID No. 462853-01].

2. The product chemistry data submitted corresponding to guideline reference 830.1600 (description of material used to produce the product) satisfy the data requirements of 40CFR§ 158.160 [MRID No. 462853-01 and MRID No. 464606-01].

3. The product chemistry data submitted corresponding to guideline reference 830.1620 (description of production process) satisfy the data requirements for 40CFR§158.162. The active ingredient was produced by [redacted] The details of the production process were provided on later date (02-02-05) which included the amounts of each starting material used in the process, description of the equipment used, the reaction conditions (temperature, pH, etc.) and the yields of the final product and the steps taken to control the quality of the product [MRID No. 462853-01 and MRID No. 464606-01].

4. *The product chemistry data submitted corresponding to guideline reference 830.1670 (discussion on* the formation of impurities) satisfy the data requirements for 40CFR§158.167. The registrant has listed [redacted] impurities [redacted]) which were identified during five batch analysis, the mechanism of formation of each of the impurities listed on the CSF have been provided [MRID No. 462853-01 and MRID No. 464606-01].

Manufacturing process information may be entitled to confidential treatment

Product ingredient source information may be entitled to confidential treatment

5. The data submitted corresponding the guideline reference 830.1700 (preliminary analysis) satisfy the data requirements of 40CFR§158.170. Five representative batches of the technical were analyzed for percent active ingredient by GC/FID method. The study was not conducted in accordance with US EPA GLP requirements. However, the applicant provided the following statement with respect to GLP: "The analyses were carried out at [redacted] which is not familiar with the US EPA Good laboratory Practices. It is, however, a laboratory with well trained staff, written procedures, and follows many internationally standard analytical protocols." The registrant provided a copy of the standard analytical SOP followed by [redacted] for conducting analytical studies, which may be considered equivalent to US EPA GLP requirements [MRID No. 462853-01 & MRID No. 464606-01].

6. The data submitted corresponding the guideline reference 830.1800 (enforcement analytical method) satisfy the data requirements of 40CFR§158.180. The GC/FID method was used to assay the active ingredient in the product [MRID No. 462853-01].

7. The data submitted corresponding to 830 series subgroup B (physical-chemical properties) for the proposed product satisfy the data requirements of 40CFR§158.190 [MRID No. 462853-01].

CONCLUSIONS:

The TRB has reviewed the product chemistry data submitted for IMS p-dichlorobenzene TGAI / MUP and has concluded that:

1. All the product chemistry data submitted corresponding to 830 Series Subgroup A are now acceptable.

2. The CSF for basic formulation (dated 05-10-04) is acceptable.

3. The 830 Series Subgroup B (physical-chemical properties) data submitted satisfy the data requirements of 40CFR§158.190 and are acceptable.

4. The proposed product (File symbol # 81433-R) was determined to be substantially similar to the registered product with Reg. No. 1475-21 from the product chemistry point of view.

5. Since the Flash point of the product was determined to be 149.9^{0}F, the registrant is recommended to add on the product label the following statement under Physical-Chemical Hazard in compliance with 40CFR§156.78: "Combustible. Do not use or store near heat or open flame".

6. The study corresponding to 830.1700 (preliminary analysis) was not conducted in accordance to GLP requirements . However, the registrant has provided the document "Sampling Method for Commodity Pesticides. GB/T1605-2001" , followed by [redacted] Considering the fact that the chemical is well known for its uses, in reviewers opinion the data submitted is sufficient to satisfy the data requirements of 40CFR§158.170. For future applications, the registrant is recommended to follow US EPA GLP requirement guidelines as described in 40CFR§160, otherwise the application may be rejected.

BARCODE:D304943; **Reg. No.** : 81433-R **PRODUCT**: IMS p-dichlorobenzene TGAI/MUP

830.1550. Product identity & Composition: (MRID No. 462853-01)

Common Name: p-dichlorobenzene

Chemical name: p-dichlorobenzene or 1, 4-dichlorobenzene

CAS No.: 106-46-7

PC Code No.: 061501

Empirical formula: $C_6H_4Cl_2$

Molecular Weight: 147

Structural formula:

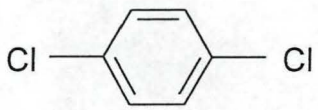

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Table 1: Manufacturing and Impurity Data for IMS p-dichlorobenzene Technical

GLN	Requirement	MRID	Status	Details and/or Deficiency
830.1550	Product identity and composition	Basic CSF (05-10-04)	A	The NC of AI (99.8%) is supported by 5 batch analysis & agree with the label claim NC. [redacted] impurities are listed on the CSF.
830.1600	Description of materials used to produce product	464606-01	A	The product specification sheets(MSDS) for all the starting materials have been provided by registrant.
830.1620	Description of production process	462853-01 & 464606-01	A	The AI was produced by [redacted] The production process has been described in full details. The reaction conditions are given, and the amounts of the reagents used in each step have been provided. The QA steps involved in each step have been described.
830.1670	Discussion of formation of impurities	462853-01 464606-01	A	The registrant has provided the complete mechanisms of formation, quantification and identification of all the impurities . Total of [redacted] impurities have been identified including [redacted] No toxic impurity was reported during the synthesis of the TGAI/MUP.
830.1700	Preliminary analysis	462853-01	A	Registrant has provided 5 batch analysis for the TGAI. The AI & impurities were determined by using GC/FID. The analysis was not done under GLP.
830.1750	Certified limits	Basic CSF (05-10-04)	A	The proposed certified limits for the AI and impurities are based on the standard certified limits.
830.1800	Enforcement analytical method	462853-01	A	The GC/FID method was used for the assay of the AI in technical. The method validated for linearity, accuracy and precision.

A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not Applicable.; G = Data gap; I = In progress or need upgrade; U = Up-grade(additional information required)

BARCODE:D304943; **Reg. No.** : 81433-R **PRODUCT**: IMS p-dichlorobenzene TGAI/MUP

830 Series Subgroup B (Physical-Chemical Properties)

Table 2: Physical and Chemical Properties of IMS p-dichlorobenzene Technical

GLN	Requirement	MRID	Status	Result or Deficiency
830.6302	C o l o r	462853-01	A	White
830.6303	Physical state	" " "	A	Crystalline solid
830.6304	Odor	" " "	A	Moth-ball like
830.6313	Stability to normal and elevated temperatures, metals, and metal ions		NA	
830.6314	Oxidation/reduction: chemical incompatibility		NA	
830.6315	Flammability	462853-01	A	65.6^0 C / 150 ^{0} F
830.6316	Explodability		NA	
830.6317	Storage stability	462853-01	A	Stable
830.6319	Miscibility		NA	
830.6320	Corrosion characteristics	462853-01	A	non-corrosive
830.7000	pH	462853-01	NA	non-dispersible in water
830.7050	UV/Visible absorption		NA	
830.7100	Viscosity		NA	
830.7200	Melting point	462853-01	NA	53.3^0 C
830.7220	Boiling point	462853-01	A	boils at 173.7^{0}C
830.7300	Relative Density	462853-01	A	1.458 @ 25 ^{0}C
830.7370	Dissociation constants in water		NA	
830.7550	Partition coefficient		NA	
830.7840	Water solubility:	462853-01	A	0.007% in water at 23^{0}C
830.7950	Vapor pressure	462853-01	A	0.40 mm Hg at 20^{0}C

A = acceptable, N = Not acceptable, U = Upgrade required, I = In progress or incomplete, W = waiver, G = Data gap, NA = Not applicable

BARCODE:D304943; **Reg. No.** : 81433-R **PRODUCT**: IMS p-dichlorobenzene TGAI/MUP

830.1800. Enforcement analytical method: (MRID No. 462853-01)

The GC/FID with internal standard method was used to assay the active ingredient p-dichlorobenzene TGAI/MUP.

Instrument & Parameters:

Instrument: GC equipped with FID
Detector: FID
Detector temperature: 225^{0}C
Inlet temperature: 225^{0}C
Carrier gas: Nitrogen with flow rate of 8.0 ml/min
Hydrogen: with flow rate of 40 ml/min
Air: with flow rate of 300 ml/min
Column: HP-5, 15 m x 0.53 mm id, meting capillary column.
Injection mode: Split ratio 20:1
Column temperature: 60^{0}C
Volume injected: 1 µL
Internal standard: methyl toluate
Retention time: approximately 4.0 min for p-dichlorobenzene; 6.8 min for Internal standard

The analytical method was validated for precision, accuracy, and linearity.

Pages 13-15 – *Manufacturing process information may be entitled to confidential treatment*